SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Nitrostat tablets (0.3 mg)

Trade Name: Nitrostat; VERNIES
Synonyms: Nitroglycerin tablets USP
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product for the treatment of angina pectoris

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 4

Label Elements

Signal Word: Warning
Hazard Statements: H302 - Harmful if swallowed

Precautionary Statements:
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards No data available

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Nitroglycerin	55-63-0	200-240-8	Acute Tox. 2 (H300) Acute Tox. 2 (H310) STOT RE 2 (H373) Aquatic Chronic 2 (H411) Acute Tox. 2 (H330) Unst. Expl. (H200)	<1.0
Glyceryl monostearate	31566-31-1	250-705-4	Not Listed	*
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	Not Listed	*
Calcium stearate	1592-23-0	216-472-8	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Nitroglycerin

ACGIH Threshold Limit Value (TWA)	0.05 ppm
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	0.05 ppm 0.46 mg/m^3
Austria OEL - MAKs	0.05 ppm 0.5 mg/m^3
Belgium OEL - TWA	0.05 ppm 0.47 mg/m^3
Czech Republic OEL - TWA	0.5 mg/m^3
Estonia OEL - TWA	0.03 ppm 0.3 mg/m^3
Finland OEL - TWA	0.03 ppm 0.3 mg/m^3
France OEL - TWA	0.1 ppm 1 mg/m^3
Germany - TRGS 900 - TWAs	0.01 ppm 0.094 mg/m^3
Germany (DFG) - MAK	0.01 ppm 0.094 mg/m^3
Germany - Biological Exposure Limit:	0.5 µg/L
Greece OEL - TWA	0.2 ppm 2 mg/m^3
Hungary OEL - TWA	0.5 mg/m^3
Ireland OEL - TWAs	0.05 ppm 0.5 mg/m^3
Japan - OELs - Ceilings	0.05 ppm 0.46 mg/m^3
Lithuania OEL - TWA	0.03 ppm 0.3 mg/m^3
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption
Poland OEL - TWA	0.5 mg/m^3
Portugal OEL - TWA	0.05 ppm
Romania OEL - TWA	0.006 ppm 0.05 mg/m^3
Slovakia OEL - TWA	0.05 ppm 0.47 mg/m^3
Slovenia OEL - TWA	0.05 ppm 0.47 mg/m^3
Spain OEL - TWA	0.05 ppm 0.5 mg/m^3
Sweden OEL - TWAs	0.03 ppm 0.3 mg/m^3
Switzerland OEL -TWAs	0.01 ppm 0.094 mg/m^3
UK - Biological Exposure Limit:	15 µmol/mol creatinine
Vietnam OEL - TWAs	0.5 mg/m^3

Glyceryl monostearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	5 mg/m^3

Silicon dioxide, colloidal NF

Australia TWA	2 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	4 mg/m^3
	0.3 mg/m^3
Czech Republic OEL - TWA	0.1 mg/m^3
	4.0 mg/m^3
Estonia OEL - TWA	2 mg/m^3
Finland OEL - TWA	5 mg/m^3
Germany - TRGS 900 - TWAs	4 mg/m^3
Germany (DFG) - MAK	4 mg/m^3
Ireland OEL - TWAs	6 mg/m^3
	2.4 mg/m^3
Latvia OEL - TWA	1 mg/m^3
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m^3
Switzerland OEL -TWAs	4 mg/m^3
	0.3 mg/m^3

Calcium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	5 mg/m^3

Starch, pregelatinized

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
Czech Republic OEL - TWA	4.0 mg/m^3
Greece OEL - TWA	10 mg/m^3
	5 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
	4 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Slovakia OEL - TWA	4 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	**Color:**	White
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Calcium stearate
No data available
Glyceryl monostearate
No data available
Lactose NF, monohydrate
No data available
Silicon dioxide, colloidal NF
No data available
Starch, pregelatinized
No data available
Nitroglycerin
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data availableThe active ingredient in this formulation is highly explosive. However, based on the amount of active ingredient contained in this product it is not expected to pose an explosion risk.
Polymerization:	Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Avoid direct sunlight, conditions that might generate heat, and sources of ignition.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: Chest pain, acute myocardial infarction, and sudden death have occurred during temporary withdrawal of organic nitrates from industrial workers exposed for long periods of time.

Known Clinical Effects: Headache, which may be severe and persistent, may occur immediately after use. Vertigo, dizziness, weakness, palpitation, and other manifestations of postural hypotension may develop occasionally. Flushing, drug rash, and exfoliative dermatitis have been reported in patients receiving nitrate therapy.

Acute Toxicity: (Species, Route, End Point, Dose)

Glyceryl monostearate
Mouse IP LD50 200 mg/kg

Nitroglycerin
Rat Oral LD50 105 mg/kg
Mouse Oral LD50 115mg/kg
Rabbit Dermal LD50 > 280mg/kg
Rat Dermal LD50 > 29mg/kg
Rat IV LD50 23.2mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Nitroglycerin
Fertility and Embryonic Development Rat Oral434 mg/kg/day NOAEL Negative
Embryo / Fetal Development Rabbit Oral 240 mg/kg/day NOAEL Not Teratogenic

Teratogenicity Teratology studies conducted in rabbits with topically applied nitroglycerin at doses up to 240 mg/kg/day were negative.

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Nitroglycerin
Bacterial Mutagenicity (Ames) *Salmonella* Positive
In Vivo Dominant Lethal Assay Rat Negative
In Vitro Cytogenetics Rat Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Nitroglycerin
2 Year(s) Rat Oral 434 mg/kg/day LOAEL Liver, Male reproductive system
2 Year(s) Mouse Oral 1058 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Silicon dioxide, colloidal NF
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Based on the concentration of the active ingredient in the formulation, No harmful effects to aquatic organisms are expected.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Nitroglycerin
Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 1.91 mg/L
Midge LC50 48 Hours 20 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Nitroglycerin
RCRA - P Series Wastes Listed

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

15. REGULATORY INFORMATION

Nitroglycerin

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	10 lb 4.54 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS/ELINCS List	200-240-8

Glyceryl monostearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	250-705-4

Silicon dioxide, colloidal NF

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4

Calcium stearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	216-472-8

Starch, pregelatinized

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

Lactose NF, monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Explosives-Unstable explsoives; H200 - Unstable explosive
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
Acute toxicity, dermal-Cat.2; H310 - Fatal in contact with skin
Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

Data Sources:	Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.
Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Revision date:	28-Mar-2016
	Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet